ATTACHMENT III – 510(k) SUMMARY, REVISED

Mondeal® Distal Radius System
510(k) Summary of Safety and Effectiveness

SEP 17 2007

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K071798. This Summary was prepared on August 27, 2007

GENERAL INFORMATION

Manufacturer and Applicant Information:

Mondeal Medical Systems GmbH
Moltkestr. 39
Tuttlingen, GERMANY 78532
Contact: Jay Evans
Telephone: 858-901-4123
Fax: 858-225-0311

Trade Name:

Device Name: Mondeal® Distal Radius System
Common Name: Screw, Fixation, Bone and Plate, Fixation, Bone
Classification Name: Plate, Fixation, Bone, Class II
and Regulation: 21 CFR 888.3030, 87HRS

Substantial Equivalence:

Mondeal Medical Systems GmbH, claims substantial equivalence to the Mondeal® Radius HO System, K050655.

Indications for Use:

The Mondeal® DISTAL RADIUS System is intended to be used for the fixation of fractures and osteotomies involving the distal radius applied to the volar and dorsal aspect.

Description of the Device

The Mondeal® Distal Radius System consists of titanium volar and dorsal plates with shapes and sizes designed for internal fixation of distal radius fractures and osteotomies, and screws of varying lengths from 8 to 38 mm and 2.7 or 3.0 mm in diameter, supplied non-sterile packaged together in either tempered plastic or stainless steel trays suitable for recommended steam sterilisation, and also individually for single implantable use. The plates include dorsal and volar "T" shaped right and left hand configurations. Manual reusable surgical instruments may be supplied to facilitate implantation.

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Device Comparison

Characteristic	Mondeal® Distal Radius System	Mondeal® Radius HO System
Names	Mondeal® Distal Radius System	Mondeal® Radius HO System
510(k) number	TBD	K050655
Indications for use	The Mondeal® DISTAL RADIUS System is intended to be used for the fixation of fractures and osteotomies involving the distal radius applied to the volar and dorsal aspect.	The Mondeal® RADIUS HO System is intended to be used for the fixation of fractures and osteotomies involving the distal radius applied to the volar and dorsal aspect.
Design and Device Characteristics		
Technology	Titanium plates and screws	Titanium plates and screws
Application	Internal Fixation of small bones of hand and foot	Internal Fixation of small bones of hand and foot
Design / Components	CP Titanium Grade 2 plates and Ti-6Al-4V ELI screws	Ti-6Al-4V ELI Anodized Type II plates and screws
Performance Specifications		
Corrosion resistance	Identical	Identical
Mechanical properties	Similar hardness, yield and tensile strength, elongation, reduction in area, chemical content	Similar hardness, yield and tensile strength, elongation, reduction in area, chemical content
Sterilisation Method	Steam Autoclave	Steam Autoclave
Packaging	Tempered plastic and or stainless steel trays suitable for steam sterilization including plate, screw, and hand tools (Class I) assortment, plates and screws also packaged individually, all non-sterils, intended for sterilization by purchaser	Tempered plastic and or stainless steel trays suitable for steam sterilization including plate, screw, and hand tools (Class I) assortment, plates and screws also packaged individually, all non-sterils, intended for sterilization by purchaser

Conclusions

Mondeal Medical Systems GmbH considers the Mondeal® DISTAL RADIUS System to be substantially equivalent to the aforementioned predicate devices with regard to intended use, materials, biocompatibility, and overall performance characteristics in accordance with the above comparison summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mondeal Medical Systems, GmbH
% Mr. Jay Evans
Mondeal North America, Inc.
13566 Freeport Road
San Diego, California 92133

SEP 17 2007

Re: K071798
Trade/Device Name: Mondeal® Distal Radius System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: August 28, 2007
Received: September 4, 2007

Dear Mr. Evans:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

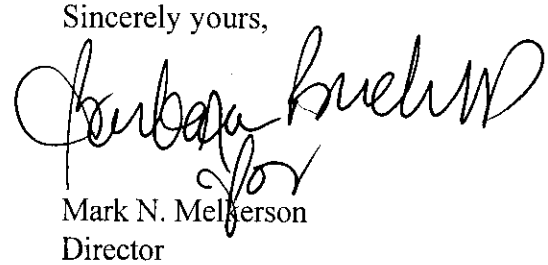
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K071798

Device Name: Mondeal® Distal Radius System

Indications For Use:

The Mondeal® DISTAL RADIUS System is intended to be used for the fixation of fractures and osteotomies involving the distal radius applied to the volar and dorsal aspect.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071798